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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,313	12/29/2000	Gerardo Castillo	PROTEO.P16	1184

7590 06/21/2004

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,313	CASTILLO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,10-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4,5,10-13 and 15-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2004 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4, 5, and 10, drawn to a method for treating, inhibiting, or managing amyloid fibril formation in Alzheimer's disease and type II diabetes via administering a therapeutic amount of green tea, green tea leaves, green tea extract, or epicatechin, classified in class 424, subclass 729, for example.

II. Claims 11 and 12, drawn to a method for treating, inhibiting, or managing *a*-synuclein fibril formation in Parkinson's disease or Lewy body disease via administering a therapeutic amount of green tea, green tea leaves, green tea extract, or epicatechin, classified in class 424, subclass 774, for example.

III. Claims 13 and 15-18, drawn to a method of promoting, supporting, and/or improving mental alertness and/or cognitive qualities/effects via administering a therapeutic amount of epicatechin, classified in class 514, subclass 456, for example.

IV. Claim 19, drawn to a method for reducing, disrupting, dissolving, inhibiting or elimination one or more conditions involving the brain consisting of various amyloid conditions/diseases via administering a therapeutic amount of epicatechin, classified in class514, subclass 456, for example.

V. Claim 20, drawn to a method for promoting or supporting healthy pancreatic function via administering a therapeutic amount of epicatechin, classified in class 514, subclass 456, for example.

VI. Claim 21, drawn to a method of treating a patient having a pancreatic disease/condition via administering a therapeutic amount of epicatechin, classified in class 514, subclass 456, for example.

VII. Claims 22-23, drawn to a method of making a pharmaceutical composition via combining green tea, green tea leaves, green tea leaf extract with an acceptable carrier and/or excipient, classified in class 424, subclass 400, for example.

The inventions are distinct, each from the other because of the following reasons:

As evidenced by the claims themselves, the methods of Groups I-VII are directed to different inventions which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone. For example, a method of treating amyloid fibril formation in a subject suffering from Alzheimer's disease and type II diabetes is different and distinct from a method of treating

a-synuclein fibril formation in a subject suffering from Parkinson's disease or Lewy body disease, either of which is different and distinct from a method of promoting, supporting, and/or improving mental alertness and/or cognitive qualities/effects in a subject in need thereof, any of which are different and distinct from a method of promoting or supporting healthy pancreatic function, any of which are different and distinct from a method of treating a patient suffering from a pancreatic disease/condition, all of which are unrelated to a method of making a pharmaceutical composition. In addition, the methods of Groups I and II do not necessarily require that the compound epicatechin be administered, whereas the methods of Groups III-VI do. Further, the preparatory method of Group VII requires that green tea, green tea leaves, and/or green tea leaf extract be employed, whereas the methods of Groups III-VI do not use green tea, green tea leaves, and/or green tea leaf extract, *per se*.

The several inventions above are independent and distinct, each from the other. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

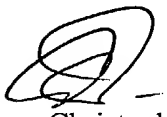
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Please note that the Examiner assigned to this Application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654